

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Medivators Inc. 3150 Pollok Dr. Conroe, TX 77303 USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits, and related accessories.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4716)

Approved by: Geraldine Larkin Chief Executive Officer Approved by: Caroline Dore Geraghty Director of Medical Devices / Head of Notified Body

Registration Number: MD19.4716 Certification Granted: May 30, 2012

Effective Date: May 16, 2019 Expiry Date: May 15, 2022





**Annex to Certificate Number: MD19.4716** 

## **Scope of Registration:**

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits, and related accessories.

Activity	Location
Administration, Manufacture, Distribution	Medivators Inc. 3150 Pollok Dr. Conroe, TX 77303 USA File No.: MD19.4716
Design & Development	Medivators Inc. 3101 Pollok Dr. Conroe, TX 77303 USA File No.: MD19.4716/A
Manufacturing	Medivators Inc. 501 North Farm to Market 3083 Rd E Conroe, TX 77303 USA File No.: MD19.4716/B
Manufacturing	Medivators Inc. 750 Conroe Park North Conroe, TX 77303 USA File No: MD19.4716/C

Verified by: Operations Ma

Operations Manager